

### **REMARKS/ARGUMENTS**

Claims 41, 43, 44, 48, 51, 52, 56, 75-77 and 79-86 are pending in this application and are presented for examination. Claims 77 and 83-85 have been amended. No new matter has been entered with the foregoing amendments. Reconsideration is respectfully requested.

#### **I. FORMALITIES**

Claims 77, 83, 84 and 85 have been amended. Claim 77 has been amended to recite that the nucleic acid molecule comprising SEQ ID NO:3 (or its complement) or SEQ ID NO:5 (or its complement) extends at a maximum 30,000 nucleotides over the 5' and/or 3' end of the nucleic acid molecule of SEQ ID NO:1. Support for this amendment is found, for example, in the paragraph bridging pages 5 and 6. A similar amendment has been made to claim 83.

Claims 84 and 85 have been amended to recite that the primer is a maximum of 24 nucleotides and consists of the sequence in SEQ ID NO:3 or SEQ ID NO:5. Support for this amendment is found, for example, in paragraph 38. In view of the foregoing support, Applicants respectfully request that the Examiner enter the amendments.

#### **II. RESTRICTION REQUIREMENT**

The Examiner withdrew the restriction requirement dated October 18, 2007. The Examiner then stated that the restriction requirement of October 11, 2006 regarding SEQ ID NO:3 is maintained. However, the aforementioned restriction requirement with respect to SEQ ID NO:3 was changed to a species election. Examiner Cho stated on page 2 of the Office Action dated January 29, 2007:

It is noted that although SEQ ID NOS: 3 and 5 were restricted from each other as drawn to different inventions (not different species) in the previous restriction requirement, because the sequences only differ by a single polymorphism, the restriction requirement between SEQ ID NOS: 1 and 3 has been changed to election of species. [Emphasis added.]

Applicants believe that the amendments herein and the remarks below place the application in condition for allowance. Applicants are therefore entitled to a reasonable number of species. As such, Applicants request that SEQ ID NO:3 be rejoined and examined on the merits.

### **III. REJECTION UNDER 35 U.S.C. § 102(b)**

The Examiner rejected claim 83 under 35 U.S.C. § 102(b) as allegedly being anticipated by Birren *et al.* To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

Applicants have amended claim 83 to recite that the polynucleotide consists of SEQ ID NO:3 (or its complement) or SEQ ID NO:5 (or its complement) and has **at most** 63,213 bases. A similar amendment has been made to claim 77.

In stark contrast, Birren *et al.* discloses a nucleic acid molecule of 177,067 bases. As such, Birren *et al.* in no way anticipates the present claim. In view of the amendment to the claim, Applicants respectfully request that the Examiner withdraw the rejection.

### **IV. FIRST REJECTION UNDER 35 U.S.C. § 103(a)**

The Examiner rejected claims 41, 43-44, 48, 51-52, 56, 77 and 79-82 under 35 U.S.C. § 103(a) as allegedly being obvious over Birren *et al.*, in view of U.S. Patent No. 5,851,769 (Gray *et al.*). To the extent that the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

The Examiner alleges that Birren *et al.* teaches a contig of 11,359 base pairs that contains SEQ ID NO:1, but acknowledges that this contig does not meet the length limitations of the instant claims (*see*, Office Action at page 6). According to the Examiner, Birren *et al.* states that the disclosed sequence is a working draft sequence which consists of 19 contigs, but that the true order of the contigs is not known and their order in the sequence is arbitrary (*see*, Office Action at page 5). As such, the Examiner contends that Birren *et al.* provides motivation for one of skill in the art to take further steps to determine that order and applies Gray *et al.* as allegedly

teaching the construction of physical maps to rapidly order contigs (*see*, Office Action at pages 5-6).

However, Applicants respectfully point out that Gray *et al.* do **not** teach or suggest how to determine the order of contigs as alleged by the Examiner. Rather, Gray *et al.* teaches the use of the methods disclosed therein for assembling physical maps which provide information on the degree of overlap between different ***clones*** (*i.e.*, cloned DNA sequences) that make up a contig (*see, e.g.*, col. 16, line 44 to col. 17, line 26). In particular, Gray *et al.* teaches that a contig comprises a group of ***clones*** representing overlapping regions of a segment of the genome and that these ***clones*** can be ordered using the quantitative DNA fiber mapping method described therein to find a set of ***clones*** which minimally overlaps with other ***clones*** but still spans the entire contig of interest (*see*, Example 3 at col. 33 of Gray *et al.*). As such, Applicants submit that Gray *et al.* merely teaches how to map overlapping ***clones*** onto a contig sequence, but fails to contemplate any method for assembling a group of non-overlapping contigs in their true order.

In addition, Applicants assert that Gray *et al.* does **not** teach or suggest the specific nucleic acid molecules comprising SEQ ID NO:1 as presently claimed. In particular, the claimed molecules contain a nucleic acid sequence of a defined length and must consist of SEQ ID NO:1 (or its complement) and have **at most** 30,000 nucleotides on the 5' and/or 3' end of the molecule. Furthermore, there is no teaching in Gray *et al.* of hypolactasia nor the association of the specific SNP as is currently claimed. As such, a skilled person would have no expectation of success of identifying the sequences as claimed, their respective SNPs, and the association of the SNPs to hypolactasia.

In view of the foregoing, Applicants submit that there is no rational underpinning between the references to support a legal conclusion of obviousness. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (U.S. 2007). Accordingly, Applicants request that the Examiner withdraw the rejection and send this application to issue.

**V. SECOND REJECTION UNDER 35 U.S.C. § 103(a)**

The Examiner rejected claims 75 and 86 under 35 U.S.C. § 103(a) as allegedly being obvious over Birren *et al.*, in view of Gray *et al.*, as applied to claims 41, 43-44, 48, 51-52, 56, 77 and 79-82, and further in view of Ahern.

Birren *et al.* and Gray *et al.* have been discussed above. Although Ahern apparently teaches reagents in kit form, there is simply no teaching of hypolactasia nor the association of the specific SNPs as is currently claimed. The combination of references does not teach all the elements of the claims. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection and send this application to issue.

**VI. THIRD REJECTION UNDER 35 U.S.C. § 103(a)**

The Examiner rejected claims 84-85 under 35 U.S.C. § 103(a) as allegedly being obvious over Birren *et al.* in view of Gray *et al.* as applied to claims 41, 43-44, 48, 51-52, 56, 77 and 79-82, and further in view of O'Neill *et al.*

Claims 84 and 85 have been amended. The claims recite that the primer is 14 to 24 nucleotides in length and consists of SEQ ID NOs 3 or 5 (or their complement) and contains position 324. There is simply no teaching or suggestion of these elements in the cited art. Accordingly, Applicants respectfully request that the Examiner withdraw the present rejection and send this application to issue.

Appl. No. 10/775,501  
Amdt. dated March 3, 2010  
Amendment under 37 CFR 1.116 Expedited Procedure  
Examining Group 1634


PATENT

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

  
Joseph R. Snyder  
Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 415-576-0300  
JS:js  
62345742 v1